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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/796,561

03/09/2004

Jose A. Diaz

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06/07/2006

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/796,561

Applicant(s)

DIAZ ET AL.

Examiner

Raymond J. Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/15/2004</u> . | 6) <input type="checkbox"/> Other: ____ |

CLAIMS 1-30 ARE PRESENTED FOR EXAMINATION

Applicants' Information Disclosure Statement filed November 15, 2004 has been received and entered into the application. As reflected by the attached, completed copies of form PTO/SB/08A, (2 sheets), the Examiner has considered the references cited by Applicants.

Specification

The disclosure is objected to because of the following informalities:

At page 1 of the present specification, the following informalities should be changed,

- (i) at line 7, "currently pending" should be deleted;
- (ii) at line 9, "set to issue" should be deleted; and
- (iii) at line 10, after "6,703,419", ---issued--- should be inserted.

Appropriate correction is required.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-18 and 21-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention

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meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.”, (see MPEP § 2173).

In claims 12, 21 and 25, the term "high" in the expression "high density chitosan" is a relative term which renders the claim indefinite. In particular, "high" does not particularly point out the intended degree of density that a given chitosan compound may have in and still be considered a "high density chitosan" as intended by Applicants. Lacking such information, the identity of those chitosan compounds that are intended to be included or excluded by the term "high" would be open to subjective interpretation and such is inconsistent with the tenor and express requirements of 35 U.S.C. §112, second paragraph.

Accordingly, the claims are deemed properly rejected.

In order to overcome the present rejection, Applicants may wish to consider amending the appropriate claims to indicate a particular density value, such as recited in present claim 1, i.e., "generally about 0.3 grams per cubic centimeter".

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicants' parent applications/U.S. Patents have been reviewed and it is deemed that the effective date for the concept of a high density chitosan having a bulk density of generally about 0.3, (see present claim 1), is that of the filing date of the present application, i.e., March 9, 2004.

The following rejection is not applicable to the other pending claims because given the disclosure of Day, (U.S. Patent No. 5,773,427), one of ordinary skill in the art would have been lead to fiber compositions containing between about 20 and 40% by weight of acacia gum and between about 10 and 30% by weight of pectin. The percentages of these ingredients in the remaining claims of Applicants are considerably lower than those disclosed by Day, (e.g., in present claim 3, "about 5%" of acacia and "about 2%" of pectin is required) and no motivation in the art can be found to lower the ingredient percentages disclosed by Day.

Claims 1, 2, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day (U.S. Patent No. 5,773,427; cited by the Examiner) in view of Johnson et al., (U.S. Patent No. 6,130,321; cited by Applicants).

Day teaches pharmaceutical compositions which may comprise a mixture of chitosan, acacia gum, guar gum, psyllium hydrocolloid and pectin which is useful for a variety of purposes including providing dietary fiber to a patient in need thereof, (see the abstract and col. 4, lines 1-12). It is further taught that it was known to combine Vitamin C, (a.k.a., ascorbic acid) with chitosan compositions in order to enhance the effect of chitosan, (see col. 1, line 67 – col. 2, line 11). Day further teaches that the composition may be presented in the form of a capsule, (see

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col. 6, line 43) and also may contain excipients such as anticaking and flow-enhancing materials, (see col. 6, lines 9-16).

The difference between the above and the claimed subject matter lies in that Day fails to highlight:

- (i) the husks of psyllium and pectin from vegetables or fruit; and
- (ii) high density chitosan having a bulk density of generally about 0.3 grams per cubic centimeter.

However, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because Day teaches psyllium and pectin in general and would not have been appreciated as being limited to any particular form/source of these fibers. The selection of any particular source/form of the fibers identified by Day would have been a matter well within the normal scope of one of ordinary skill in the art's knowledge and/or skill. Also, the tenor of Day is to employ chitosan in general and to not be limited to any particular type/source. Given this latitude, one of ordinary skill in the art would have appreciated that any type of chitosan or source of chitosan would have been useful for the purposes disclosed by Day. A particular type of chitosan that was known to the artisan is disclosed by Johnson et al. In particular, Johnson et al. disclose a chitosan having a tap density of at least about 0.4 g/ml, (a.k.a. grams per cubic centimeter). One of ordinary skill in the art would have been motivated to employ such a form of chitosan in order to achieve the benefits taught by Johnson et al. of having better flow characteristics and therefore better dispensed in dosage forms such as capsules, (see col. 1, lines

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53-62). The present claims require a density of “generally about 0.3” g/cc and such is not patentably distinct from a value of 0.4, as taught by Johnson et al.

Accordingly, the claims are deemed properly rejected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of Applicants’ U.S. Patent No. 6,703,419, (cited by Applicants) in view of Johnson et al., (U.S. Patent No. 6,130,321; cited by Applicants).

The difference between the presently claimed subject matter and that of the ‘419 patent lies in that a high density chitosan is presently employed, while in the patented claims, a “natural marine shellfish extract” is claimed. Using the patented specification as only a dictionary, the expression “natural marine shellfish extract” would encompass a chitosan ingredient, (e.g., see the ‘419 patent at col. 4, lines 45-50).

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However, to use the chitosan of the present claims rather than the natural shellfish extract of the patent claims would have been obvious because both are chitosan products and given the disclosure of Johnson et al., one of ordinary skill in the art would have been motivated to employ the high density chitosan of the present claims. In particular, from Johnson et al., not only was a chitosan having a tap density of at least about 0.4 g/ml, (a.k.a. grams per cubic centimeter and not patentably distinct from the presently claimed density of 0.3) known, but one of ordinary skill in the art would have been motivated to employ such a form of chitosan in order to achieve the benefits taught by Johnson et al. of having better flow characteristics and therefore being better dispensed in dosage forms such as capsules, (see col. 1, lines 53-62).

Accordingly, the claims are deemed properly rejected.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Raymond J Henley III
Primary Examiner
Art Unit 1614

June 1, 2006



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